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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,582	03/04/2002	Guixue Yu	HA0768 NP	5031

23914 7590 11/28/2003

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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 11/28/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/090,582

Applicant(s)

YU ET AL.

Examiner

Celia Chang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1,3-8 and 11-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,3-8, 11-16 and 18-22 is/are rejected.
- 7) ☐ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

### DETAILED ACTION

1. Amendment and response filed by applicants in Paper No. 8, dated Sep. 8, 2003 have been entered and considered carefully. Claims 2, 9, 10 have been canceled. Claims 1, 3-8, 11-22 are pending.
2. The rejection of claims 1-6, 12-16 under 35 USC 112 first paragraph is maintained for reason of record.

Applicants argued that one skilled in the art would know how to prepare the prodrug in view of the references recited by applicants. Please note that no copy of the reference was provided thus any evaluation of the descriptive support from the recited references cannot be made. In addition, the support for preparation of prodrug commonly employed in preparation of a metabolic degradable precursor as delineated in the previous office action, does not offer description or enabling support for the broad scope of "prodrug" without description. Applicants are urged to consult page 19 of the specification and claim or argue in consistency with the disclosure of the specification. It is recommended that the descriptive support be incorporated in the claims i.e. "a metabolically degradable prodrug of the functional groups".

Applicants argument that the term "wherein two....are joined to form a fused ring" finds ample information in the specification to enable one of skill in the art. This is not persuasive. Please note that initially, it is pointed out that the elected invention are the species of claims 16-17 which does not include any spiro compounds, thus, the scope wherein R8-R9 forms a ring is not within the election.

Further, wherein R13-R14 or R14-R15 forms fused ring lacks descriptive support for such scope. Please note that "none" of the exemplified compounds gave guidelines to the above

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scope and specific descriptive for the above scope finds no support in the specification. One skilled in the art may be able to make the compounds *if one knows what it is*. In absence of any descriptive support or exemplified guidelines, the rejection of claims 1-6, 12-16 is maintained for reason of record.

3. The rejection of claims 21-22 under 35 USC 112 first paragraph is maintained for reason of record.

It is unclear what is the scope of the amended claims with respect to “treating a melancortin receptor associated condition by agonizing melancortin receptors”. It is very confusing is the method on receptor function or on treating disorder. Please note that manipulation receptor activity *without* pathological outcome is absent of utility. The manipulation must have an “effect” which can obviate undesirable physiopathology to be patentable under 35 USC 101 i.e. having “use”. Mere manipulation without effect is not within the scope of “use”. It is recommended that the term “A method of treating a disease or disorder treatable by melancortin receptor agonism comprising administer an melancortin receptor agonistic effective amount ....”.

4. The rejection of claims 1-2, 4-5, 7-8, 10, 14, 18, 21-22 under 35 USC 102(e) over US 6,458,790 is dropped in view of the amendment that  $y$  is at least 1.

5. The rejections of claims 1-2, 4-5, 7-8, 10, 14, 18, 21-22 under 35 USC 103(a) over US 6,458,790 or of claims 1-5, 7-8, 10-16 over US 5,622,973 in view of US 6,303,620 are maintained for reasons of record.

It is unclear what is the scope of the amended claims. On one hand it was provided that  $y$  is at least 1, yet it was also defined in the claims that  $y$  is 0-4. If  $y$  is at least 1, then the range

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of y cannot be 0-4 but limited to 1-4. It is recommended that consistent definition be made in the claims.

To the extent that y is at least 1, then the claims are still drawn to the "1 methylene" inserted compounds of the prior art which are considered structural prima facie in absence of unexpected result (see In re Mehta cited in the previous office action). An argument with respect to utility must be support with factual evidence. It is immaterial that applicants utility may differ from that of the art. Arguments regarding utility must be based on a meaningful showing of an unexpected difference in properties of applicants compounds versus the compounds of the prior art (In re Hock 166 USPQ 406, In re Pane 203 USPQ 247). Please note that, the modified compound which is a homolog of the prior art compound, is *expected* to have homologous activity as the art unless factual evidence indicated otherwise.

6. The objection of claim 17 is maintained for reason of record.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

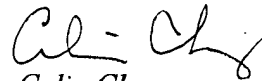
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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner can be reached by facsimile at (703) 308-7922 with courtesy voice message supra.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

OACS/Chang  
Nov. 25, 2003

  
Celia Chang  
Primary Examiner  
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